

## REMARKS

The Office Action mailed 12 February 2004, has been received and its contents carefully noted. The pending claims, claims 17-27 and 40-46, were rejected. Reconsideration in view of the following amendment and remarks is respectfully requested. By this amendment, claims 17-20, 22, 40, and 43 have been amended. Support may be found throughout the specification and claims as originally filed. For example, see Example 4. No statutory new matter has been added. Entry of the amendment and reconsideration are respectfully requested.

### **New Matter Rejection under 35 U.S.C. 112, first paragraph**

The Examiner rejected claims 17-24, 26-27 and 40-46 under 35 U.S.C. 112, first paragraph, for lack of written description support.

#### *Claim 17*

Specifically, the Examiner deemed that the phrase “inducing an mean ELISA antibody titer of about  $1 \times 10^2$  against ricin toxin” is new matter since it was not in the specification and claims as originally filed.

Applicants respectfully point out that the specification as originally filed provides written description support for “inducing an mean ELISA antibody titer of about  $1 \times 10^2$  against ricin toxin”. For an example of such support, Applicants point to Figure 3 and the specification on page 17, lines 23-27. The specification also clearly provides how the subjects were immunized and the method of testing. Therefore, claim 17 and its dependent claims are clearly supported in the specification as originally filed and the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn.

#### *Claims 19, 26 and 41*

The Examiner rejected claims 19, 26, and 41 under 35 U.S.C. 112, first paragraph, for lacking written description support for the phrase “deglycosylated ricin A-chain is incompletely deglycosylated”.

Applicants respectfully point out that although the specification does not specifically recite “incompletely”, the specification as originally filed does in fact provide support for incomplete deglycosylation. For example, on page 7 of the specification, lines 29-35 and

continuing on page 8 through line 3, it is stated that the provided procedures can result in destruction of about 50% of mannose residues. Applicants respectfully point out that 50% is not “completely”, but rather 50% is “incomplete”. Therefore, the specification as originally filed provides written description support for “incomplete deglycosylation” and the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn.

#### *Claim 22*

The Examiner rejected claim 22 under 35 U.S.C. 112, first paragraph, as lacking written description support. Specifically, the Examiner deemed that the specification does not support the phrase “the immunogenic amount is about 0.1 µg to about 10.0 µg per about 20 g to about 25 g of the weight of the subject”.

Applicants respectfully submit that the claims have been amended to recited the ranges that the Examiner pointed out were supported in the specification. Therefore, Applicants respectfully submit that the claims as amended are supported and the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn.

#### **Rejection under 35 U.S.C. 112, second paragraph**

The Examiner rejected claims 17-24 and 40-46 under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the Examiner stated that claim 17 does not disclose the units of measurements for the titer and that it is unclear whether “more” referred to the titer or ricin toxin.

Applicants have amended claim 17 in order to clarify that the units is mg/ml and that “more” refers to the titer amount. Support may be found in the specification generally. Specifically, Applicants respectfully point out that one skilled in the art would understand that, in the context of the specification, the units are mg/ml and “more” refers to the titer as other such titer amounts are expressly provided in mg/ml. Therefore, the rejection under 35 U.S.C. 112, second paragraph, should properly be withdrawn.

#### **Rejection under 35 U.S.C. 102(b)**

The Examiner rejected claims 17, 18, 21-25, 40 and 42-46 under 35 U.S.C. 102(b) as being anticipated by the ‘271 patent. Specifically, the Examiner deemed that the recombinant

ricin A-chain is the same as the chemically deglycosylated ricin A-chain of the present invention because producing proteins in bacterial systems results in proteins that lack glycosylation.

Applicants respectfully submit that the specification clearly points out that the claims as amended, i.e. chemically deglycosylated ricin A-chain contains about 50% of the mannose residues of the wild-type ricin toxin A-chain. As the Examiner pointed out, a recombinant protein expressed in bacterial systems completely lacks glycosylation. It is well known in the biotech arts that the presence or absence of sugar residues on proteins affects the biological and chemical properties of the proteins. Therefore, one protein having some sugar residues is not the same as another protein having the same amino acid sequence, but completely lacking any sugar molecules. Clearly, the recombinant prior art ricin A-chain is not the same composition as the chemically deglycosylation ricin A-chain encompassed in the claims as amended.

Therefore, the methods of the present invention involving the use of a chemically deglycosylated ricin A-chain are novel and the rejection under 35 U.S.C. 102(b) should properly be withdrawn.

#### **Request for Interview**

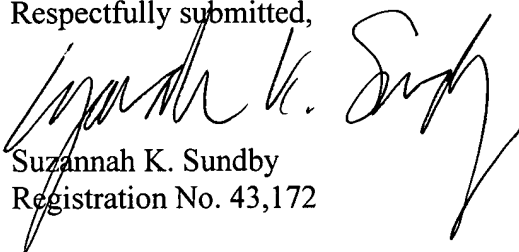
Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

## CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. **210-380**, referencing Attorney Docket No. **034047.004.1 (RIID 99-12A)**.

Respectfully submitted,



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